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EXAMINER

FIELD, TAMMY K

ART UNIT

PAPER NUMBER

1645

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

# Office Action Summary

Application No.

10/067,124

Applicant(s)

OITA, SHIGERU

Examiner

Tammy K. Field

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Detailed Action***

1. Claims 1-3 are pending and under examination.

***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statement (IDS)***

3. The IDS filed on February 4, 2002 has been considered, signed, and initialed, and a copy is enclosed. For references with only an English Abstract supplied, the pages referring to other pages within the article have not been considered.

***Claim Objections***

4. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent Claim 1 reads on a bactericidal composition, whereas dependent claim 2 reads on the bactericidal composition and the intended use of the composition. The recitation of an intended use of "bacterial composition for food poisoning bacteria" property for a composition containing same in a dependent claim, must result in a tangible structural difference between the composition of the independent claim and that of the dependent claim, said dependent claim is seen to be not further limiting, and said recitation is not afforded critical weight and fails to further limit the composition of said dependent claim. Therefore the composition of claim 2 does not function to further structurally limit the composition of claim 1, and will not be given patentable weight.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-2 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 13 of U.S. Patent No. 6,329,011 B1 by Oita in view of Garcia-Olmendo *et al.* (US Patent 5,446,127 issued August 29, 1995).

The instant application's claims are drawn to a bactericidal composition comprising as effective ingredients (a) ethylenediaminetetraacetic acid (EDTA) and metal salts (content is 0.05mM or more and less than 1.5mM) and (b) alpha-type thionin or beta-type thionin (content 1 µg/ml or more and 150 µg/ml or less).

Oita claims are drawn to a composition comprising a thionin wherein said thionin is selected from the group consisting of an alpha-type thionin in an amount ranging from 5 to 100 µg/ml and a beta-type thionin in an amount ranging from 10 to 100 µg/ml (see claims 1-4 at column 5, lines 18-27). Oita further recites in claim 13 a method of inhibiting the growth of an acid-resistant or heat-resistant bacteria belonging to the genus *Alicyclobacillus*, comprising contacting said bacterium with an effective amount of a thionin (see claim 13 at column 6, line

19-22). Oita differs from the instant claimed invention because EDTA and EDTA salts are not part of the claimed composition.

Garcia-Olmendo *et al.* teaches the limitations of a bactericidal composition comprising  $\alpha/\beta$ -thionin peptides and a metal chelator such as EDTA to prevent exposure of the protein to heavy metal ions that might inactivate the protein at column 3, line 63-column 4, line 49 and at column 16, lines 20-24.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the limitation of EDTA in the composition of alpha-type thionin and beta-type thionin because together these ingredients enhance the effectiveness of a bactericidal composition.

This is an obviousness-type double patenting rejection.

6. Claims 1-3 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. US Patent Application Publication 2002/0058696 by Nagai and Oita, in view of Garcia-Olmendo *et al.* (US Patent 5,446,127 issued August 29, 1995).

Nagai and Oita claims are drawn to an antibacterial agent for *Helicobacter pylori*, comprising at least one substance selected from the group consisting of ethylenediaminetetraacetic acid and its metal salts as an effective component (see claim 1 at page 2, paragraph 0029). Nagai and Oita further recite in claim 2 the antibacterial agent for *Helicobacter pylori* according to claim 1, wherein the metal salt of ethylenediaminetetraacetic acid is disodium ethylenediaminetetraacetate or iron (III)-sodium ethylenediaminetetraacetate. Nagai and Oita further disclose *Helicobacter pylorus* is inhibited by means of 0.025-1 mM

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disodium ethylenediaminetetraacetate and 0.1-0.5 mM iron(III)-sodium ethylenediaminetetraacetate (page 2, paragraph 0026 and Figs. 1 and 2). Nagai and Oita differs from the instant claimed invention by not adding thionin to the composition.

Garcia-Olmendo *et al.* teaches the limitations of a bactericidal composition comprising the addition of the proteins of  $\alpha/\beta$ -thionin at column 3, line 63 – column 4, line 49; column 16, lines 20-24 and Fig. 1. A composition consisting of a concentration of 1  $\mu$ M of  $\alpha/\beta$ -thionin was used to inhibit the growth of bacteria (column 18, lines 44-68 and Fig. 1)

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the limitation of 1  $\mu$ M of  $\alpha/\beta$ -thionin in the composition of either 0.025-1 mM disodium ethylenediaminetetraacetate or 0.1-0.5 mM iron(III)-sodium ethylenediaminetetraacetate ethylenediaminetetraacetic acid (EDTA and metal salt) because  $\alpha/\beta$ -thionin, EDTA and metal salts suggests a bactericidal composition with enhanced antimicrobial activity.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Garcia-Olmendo *et al.* (US Patent 5,446,127 issued August 29, 1995).

The instant application's claims are drawn to a bactericidal composition comprising as effective ingredients (a) ethylenediaminetetraacetic acid (EDTA) and metal salts (content is 0.05mM or more and less than 1.5mM) and (b) alpha-type thionin or beta-type thionin (content 1µg/ml or more and 150 µg/ml or less).

Garcia-Olmendo *et al.* discloses an antipathogenic composition wherein the preferred lytic peptide is an  $\alpha/\beta$ -thionin and a metal chelator such as EDTA is used to prevent exposure of the protein to heavy metal ions (column 3, lines 22-30; column 3, line 63 – Column 4 and Fig. 1). During protein purification, EDTA is added, therefore, becoming part of the composition (column 16, line 17 – 24).

The antipathogenic composition comprising thionin and EDTA that is more specifically taught by Garcia-Olmendo *et al.* to be antibacterial, is indeed a bactericidal composition comprising  $\alpha/\beta$ -thionin (column 1, lines 22 – 30; column 18, lines 44 – 68). As such, the doses and compositions taught by Garcia-Olmendo *et al.* anticipate the instant claims 1 and 2.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3 rejected under 35 U.S.C. 103(a) as being obvious over Lawyer, *et al.* (US Patent 6,042,848 issued March 28, 2000) in view of Garcia-Olmendo *et al.* (US Patent 5,446,127 issued August 29, 1995).

The instant application's claims are drawn to a bactericidal composition comprising as effective ingredients (a) ethylenediaminetetraacetic acid (EDTA) and metal salts (content is 0.05mM or more and less than 1.5mM) and (b) alpha-type thionin or beta-type thionin (content 1µg/ml or more and 150 µg/ml or less).

Lawyer, *et al.* teaches a composition for maintaining or enhancing the biological activity of antimicrobial peptides for the control of gram positive/negative bacteria at page 1, lines 42-65. Lawyer, *et al.* teaches an antimicrobial composition comprising a peptide selected from the group consisting of thionins and copper salts selected from the group consisting of copper EDTA (see claim 1 at column 9, lines 50-57). Lawyer, *et al.* also teaches the antimicrobial effective concentration of peptide is in the range of from about 0.001 µg/ml to about 500 mg/ml, and the effective concentration of copper metal is in the range of from about 0.05 µg/ml to about 7.5 mg/ml at column 7, line 53- column 8, line 45. Lawyer, *et al.* does not specifically identify thionins as alpha-type thionin or beta-type thionin.

Garcia-Olmendo *et al.* teaches the limitations of a bactericidal composition comprising the addition of the proteins of  $\alpha/\beta$ -thionin at column 3, line 63 – column 4, line 49; column 16, lines 20-24 and Fig. 1. A composition consisting of a concentration of 1 µM of  $\alpha/\beta$ -thionin and a metal chelator such as EDTA was used to inhibit the growth of bacteria (column 18, lines 44-68 and Fig. 1).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to combine the ingredients of EDTA and thionins of Lawyer, *et al.* with the ingredients of  $\alpha/\beta$ -thionin of Garcia-Olmendo *et al.* in a bactericidal composition. One would have been motivated to employ the ingredients in a bactericidal composition because



Lawyer, *et al.* and Garcia-Olmendo *et al.* both teach enhancement of antimicrobial activity with the composition. It would have been expected, barring evidence to the contrary, that the composition would be effective in controlling bacterial activity.

### ***Conclusion***

11. No claims are allowed.

12. The prior art of record and not relied upon is considered pertinent to applicant's disclosure.

(a) Oita, S. 2000. 1978. Extraction and enzymatic degradation of antimicrobial peptides,  $\alpha$ ,  $\beta$ -thionins from barley and wheat. J. of Jap. Soc. for Food Science and Tech., Vol 47, abstract only teaches that  $\alpha$ ,  $\beta$ -thionins are antimicrobial compounds.

(b) Wilhoit, D.L. 1996. US Patent 557,3800 A, teaches peptides and the chelating agent, EDTA in an antibacterial composition.

(c) Caaveiro, J.M., et al. 1998. Protein Science Vol 7, pgs. 2567-2577, teaches thionins constitute a well-defined group of low molecular weight peptides with toxic effect on bacteria.

(d) Fraser, J.R., et al. 2001. US Patent 6,180,604 B1, teaches a composition of thionins and EDTA in a composition for food preservation.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (703) 305-4447.


The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909.

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Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Tammy K. Field  
September 23, 2003

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SUPERVISORY PATENT EXAMINER  
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